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Ms. Kirsten Mortimer
c/o Regulatory Policy Division
Bureau of Industry and Security
U.S. Department of Commerce
Room 2099B
1401 Constitution Ave, NW
Washington, DC 20230

Subject: Comment on Advanced Notice of Proposed Rulemaking Regarding Review of Controls for Certain Emerging Technologies

References: 83 Fed. Reg. 58201 (Nov. 19, 2018) and 83 Fed. Reg. 64299 (Dec. 14, 2018); RIN 0694-AH61; Docket # 180712626-8840-01

Dear Ms. Mortimer:

The Biotechnology Innovation Organization ("BIO") appreciates the opportunity to respond to the Advance Notice of Proposed Rulemaking ("ANPRM") regarding the Review of Controls for Certain Emerging Technologies. BIO is the world's largest trade organization in the biotechnology sector, representing over 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States. BIO member companies vary in size, technologies, manufacturing capacity, and product range, but they are all highly innovative, heavily invested in research and development, require significant amounts of domestic and foreign investment, and access to foreign markets to continue leading global innovation in biotechnology.

BIO recognizes the Administration's objective to identify and control emerging technologies that are essential to national security and not currently subject to export controls, in line with the standards set forth in the Export Control Reform Act of 2018 ("ECRA"), 50 U.S.C. §§ 4801-4851. While we support this overarching objective, we encourage the Administration to move with extreme caution to avoid unintended harm to U.S. domestic research and development of novel biotechnologies, U.S. international competitiveness, and economic growth. The biotechnology industry is an inherently global ecosystem and utilizes global clinical research partnerships to develop promising technologies that pioneer breakthroughs to heal, feed and fuel the world.

It is critical for innovative U.S.-based biotechnology companies to participate in research alliances across borders due to the unique economic characteristics of product development. Drug development, the largest sub-industry of biotechnology, has one of the lowest product development success rates of any industry, with less than 10% of clinical programs reaching

the market. The cost to develop a single drug has been estimated to exceed $1.4 billion in direct costs and $2.6 billion in total economic costs, amounts that require diverse funding sources that often include ex-U.S. investment.[1] Furthermore, U.S. biotechnology companies must attract and retain the best talent[2] from across the world in order to maintain the U.S.'s place as the chief hub of innovation. Participation in international markets also contributes to U.S. company growth and leadership in this rapidly changing industry.

Accordingly, we urge the Administration to fully assess the potential impact of export controls on biotechnologies on "the impact on the economy of the United States" and on the sustainability of the U.S.'s global leadership in biotechnology, and pursue them "only to the extent necessary" to ensure national security, in accordance with the ECRA statement of policy for export controls in section 4811(1). Before proposing export controls on specific biotechnologies, the Commerce Department should assess the impact of each potential export control on the health of the biotechnology and life sciences ecosystem by evaluating the impact on domestic research, investment into U.S. companies developing or utilizing those technologies, and their ability to recruit and retain skilled talent necessary to develop or deploy those technologies.

With these comments and any other engagements with the Administration related to the ANRPM, BIO is not supporting or opposing the imposition of any new export controls on any particular technology. Rather, BIO is providing responses to the questions asked in the ANPRM, particularly with respect to the standards BIS should use when determining what should and should not be controlled as "emerging" technology. The emerging technology topic of relevance to BIO and its members is "[b]iotechnology, such as (i) nanobiology; (ii) synthetic biology; (iii) genomic and genetic editing; or (iv) neurotech". Further, technology is rapidly evolving, and the biotechnology industry is increasingly adopting transformational technologies from other sectors to save lives, alleviate human suffering, expand access to nutritious food sources, and improve the environment. We believe that should continue without disruption unless justified due to specific and identifiable national security concerns. The broad categories identified in the ANPRM encompass a diverse range of promising technologies, and it is unclear what specific technologies should be considered "emerging" given the lack of clarity as to what national security risks the Administration is seeking to address. In developing new proposed export controls such as those under consideration by the Department of Commerce, it is important to ensure that any proposed controls are science-based and technology-specific, to avoid overly burdensome regulations that hinder U.S. economic growth and international competitiveness, with no corresponding benefit to national security.

We respectfully submit the following comments, which are intended to aid in BIS's assessment of whether additional export controls on certain biotechnologies are "essential" to protect national security:

- We offer several parameters to consider in defining what constitutes "emerging technologies" (see BIO comment 1);
- BIS should justify each proposed control to clarify how it meets the statutory standards in ECRA (see BIO comment 2);
- "Emerging technologies" should be specific technologies that are not now controlled but that are essential to the national security of the U.S. (see BIO comment 3);
- The Administration needs to identify specific national security threats that it aims to address through new export controls on "emerging technologies" (see BIO comment 4);

- Proposed controls should be limited to addressing national security concerns, not trade policy issues (see BIO comment 5);
- "Emerging technologies" identified for control should be exclusive to the United States (see BIO comment 6):
- Technologies should not be defined as "emerging" if a unilateral control would harm research and development in the United States (see BIO comment 7);
- BIS should not impose controls over "emerging technology" that would be ineffective at preventing their proliferation to countries of concern (see BIO comment 8);
- BIS should neither propose nor impose new "emerging technology" controls unless it has fully considered the impact such controls would have on the U.S. economy (see BIO comment 9);
- BIS should propose and impose controls that are tailored to focus on core technologies (see BIO comment 10); and
- Proposed controls on emerging technologies should be of a type that will likely be considered acceptable by the relevant multilateral regime and consistent with the types of technologies controlled by the regimes (see BIO comment 11).

Finally, based on experience with public comments, it can be anticipated that only a fraction of those companies to be affected by the proposed control will comment publicly on it. This is especially likely given the complex and narrow information needed and the current relative obscurity of the export controls process within the biotechnology industry generally. Thus, BIO suggests that no negative inference should be drawn from a company's lack of comment on its technology in this ANPRM or at other stages in the process. Rather, we suggest that at each stage, BIS should independently consider and articulate the implications of proposed controls, even in the absence of specific industry comment. For example, even without industry input, BIS should independently consider and articulate how technology is unique to the United States and how a proposed control would aid in keeping it so.

I. STATUTORY BACKGROUND

To guide our response to BIS's requests, it is important to set out in one place the statutory standards governing this effort. Specifically, ECRA section 1758 requires the Administration to conduct an interagency effort to identify "emerging" technologies that "are *essential* to the U.S. national security" (emphasis supplied) and that are not now described on one of the lists of technologies the U.S. controls for export. ECRA does not define "national security," the ANPRM includes illustrative examples of now-uncontrolled commercial technologies to be reviewed for national security concerns, i.e., those that "have potential conventional weapons, intelligence collection, weapons of mass destruction, or terrorist applications or could provide the United States with a qualitative military or intelligence advantage." These examples track ECRA's definition of a "dual-use" item, which is an item that has "civilian applications and military, terrorism, weapons of mass destruction, or law-enforcement-related applications" [Id. § 4801(2)].

In deciding whether to identify such a technology as "emerging" and impose controls on its export, ECRA section 1758(a)(2)(B) requires the Administration to take in to account:

i. the development of emerging technologies in foreign countries;

ii. the effect export controls imposed pursuant to this section may have on the development of such technologies in the United States; and

iii. the effectiveness of export controls imposed pursuant to this section on limiting the proliferation of emerging technologies to foreign countries.

Section 4817 is an element of the broader ECRA statement of policy for export controls in section 4811(1), which is that the United States should "use export controls only after full consideration of the impact on the economy of the United States and only to the extent necessary -- (A) to restrict the export of items which would make a significant contribution to the military potential of any other country or combination of countries which would prove detrimental to the national security of the United States; and (B) to restrict the export of items if necessary to further significantly the foreign policy of the United States or to fulfill its declared international obligations."

ECRA sections 4811(5) and (6) state that:

> "(5) Export controls should be coordinated with the multilateral export control regimes. Export controls that are multilateral are most effective, and should be *tailored* to focus on those *core technologies* and other items that are capable of being used to pose a *serious* national security threat to the United States and its allies." (emphasis supplied)
>
> "(6) Export controls applied unilaterally to items widely available from foreign sources generally are less effective in preventing end-users from acquiring those items. Application of unilateral export controls should be limited for purposes of protecting *specific* United States national security and foreign policy interests." (emphasis supplied)

Consistent with these standards, section 4817(c), states that the Administration "shall propose that any technology identified pursuant to [this emerging technologies identification effort] be added to the list of technologies controlled by the relevant multilateral export control regimes." Although the provision allows for consideration of continued unilateral controls if the regime efforts are unsuccessful after three years, an implication of this provision is that the Administration should identify emerging technology controls with which the relevant multilateral regimes are reasonably likely to agree and that are consistent with the regimes' scope of authority.

Finally, both ECRA and the ANPRM refer only to possible additional controls on emerging "technology." ECRA section 4801(11) defines "technology" as including "information, in tangible or intangible form, necessary for the development, production, or use of an item." Section 4801(7) defines "item" as a "commodity, software, or technology." Thus, the scope of the ANPRM is limited to possible new controls on information that is within the scope of the term "technology" and does not include possible new controls on commodities or software.

II. BIOTECHNOLOGY IS A GLOBAL FIELD

The biotechnology industry is an inherently global ecosystem and utilizes global clinical research partnerships to develop promising technologies that pioneer breakthroughs to heal, feed and fuel the world. Developing biotechnologies is a highly collaborative

endeavor, and it is critical for innovative U.S.-based biotechnology companies to participate in research alliances across borders and participate in international markets in order to maintain America's place as the chief hub for innovation in this field. With the global ecosystem of biotechnology in mind, we encourage BIS to consider the following:

- Many of the challenges faced in biotechnology are global. To successfully address global health, agricultural, and industrial and environmental challenges, biotechnology platforms built by US-based companies are designed to deliver products in key markets across the globe. For instance, technology platforms for genome editing and associated intellectual property are developed in global centers for excellence. Strategic placement of these centers allows US-based companies to access leading experts in other countries. These technology platforms enable product development for the global marketplace. Further, the application of technologies such as genetic modification and genome editing can only result in successful product development if work products can be tested and validated in key global target markets. Thus, the successful delivery of global biotechnology products is highly dependent on unencumbered flow of technology and information between countries.

- The biotechnology industry has an enduring history of publishing and disseminating ideas to spur innovation and the development of products to improve human health. Placing export controls on certain areas of the biotechnology industry, particularly where there is already ample published research and scientific articles, may not impede the development of those technologies overseas, as global researchers already have access to scientific research in academic and peer-reviewed journals.

- Breakthroughs in biotechnologies rely on highly specialized talent from around the world, which is already a key challenge for U.S. companies operating in an intensely competitive global market.[3] Accordingly, we urge that BIS use caution in deciding whether and when to place controls on "deemed exports," as biotechnology innovators must be able to attract and retain the best talent from around the world in their scientific field of expertise in order to remain competitive.

- Technologies being developed in the biotechnology, nanobiology, synthetic biology, genomic and genetic editing, and neurotech areas have great potential to revolutionize and grow multiple sectors across the economy, from health to food and agriculture. Countries around the world are investing significantly in these fields, as they hold considerable promise to improve their economies and society. Accordingly, as Commerce assesses the foreign availability of "emerging" technologies in the biotech field, we encourage BIS to review the existence of fundamental research, global research partnerships, and patents, among others, as key indicators that such technologies are already being developed in foreign markets and are thus not good candidates for export control.

III. HOW "EMERGING TECHNOLOGIES" SHOULD BE DEFINED

BIS's first request for comment is about how the Administration should define emerging technologies. This request is not for advice about abstract generally applicable definitions. Rather, it is about how the term should be defined in the context of export controls to address the policy concerns that motivated ECRA. Thus, we suggest that the definition be structured around and be bounded by the statements of policy in ECRA for why the export control system exists and what it is designed to accomplish both generally and specifically

with respect to this effort, as described above. Also, given that section 1758 is focused on identifying both emerging and foundational technologies, a definition should not include foundational technologies, which are generally considered mature technologies already in production.

A. BIO Comment 1 – Parameters to consider in defining what constitutes "emerging technologies" in the biotechnology industry

We encourage BIS to consider the unique aspects of the biotechnology industry in defining what constitutes "emerging technologies" that could be subject to export controls. For instance, while it is clear that "fundamental research" is not subject to the export control regime, there need to be bright lines as to what is (not) covered by the Export Administration Regulations (EAR) in the definition of "emerging technologies."

The biotechnology industry's core foundation is fundamental research, primarily performed in academic research institutions. Discoveries made in the academic research setting, as well as those made by biotechnology and pharmaceutical companies, undergo rigorous review by the broader community, and are overwhelmingly published in research journals. In order for biotechnology companies to attract the significant investments necessary to fund their lengthy R&D periods, investors require a thorough understanding of the technologies and science underpinning their potential. Therefore, investment in biotechnology depends in large part on publication of key aspects of the research in peer-reviewed journals to vet the science. The few innovations not presented to the public in the form of research articles ultimately emerge in the public domain in the form of detailed patent filings. These industry characteristics should be reflected in the definition of "emerging technologies" to reiterate the exclusion of fundamental research. As you know, EAR section 734.3(b)(3) states that the following types of information are not subject to the EAR, regardless of their content: (i) "published" information; (ii) information that arises during, or results from, "fundamental research;" (iii) information released by instruction in academic institutions; (iv) information in patents and published patent applications; (v) information that is a non-proprietary system description; and (vi) certain types of telemetry. Each of these elements of the regulatory exclusion is further defined in this and related EAR provisions. The broader point of our comment here is that BIS, as noted on page 58202 of its notice, is not considering the imposition of controls on such types of information – i.e., information "not subject to the EAR" -- as part of this process. We ask that BIS reinforce this point often because there is considerable uncertainty among our members, investors, academic partners, foreign customers, and others regarding whether BIS will take action that will somehow limit fundamental research as a matter of law, policy, or perception. Because such research is vital to the health of our industry, we ask BIS to make this point clear.

Beyond fundamental research, the biotechnology industry requires exceptionally long research and development periods to create novel therapeutics or breakthroughs in food, agricultural, industrial and environmental technologies. Most companies spend 10-15 years in the lab or clinic conducting research to prove feasibility, safety and efficacy of the technology before reaching their first breakthrough. Accordingly, depending on the definition of what constitutes "emerging technology" adopted by BIS, much of the industry's most promising advances could be perceived—particularly during the rulemaking process—as being likely to be controlled, which could have a chilling effect on investment and innovation in these worthy areas. To instill confidence and clarity, we encourage BIS to establish bright lines as to what constitutes "emerging" technology in the biotechnology

field, to avoid unintentionally capturing a broad array of biotechnologies across many stages of development (pre-clinical and clinical or pre-launch and scale-up).

Thus, we propose that BIS consider the following in its definition of "emerging technologies":

> "Emerging technologies" should be specific non-mature core "technologies" in "development" that are essential to the national security interests of the United States and:
>
> (i) are "required" for the "development" of specific and identifiable conventional weapons, intelligence collection applications, weapons of mass destruction, or terrorist applications;
>
> (ii) would provide the United States with a specific and identifiable qualitative military or intelligence advantage;
>
> (iii) are not available in or otherwise being developed in foreign countries; and
>
> (iv) are not within the scope of any existing multilateral controls.
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> Note: A "technology" must not be identified or controlled as "emerging" unless it is within the scope of policy statements in ECRA for which "technologies" should be controlled for export. In particular, ECRA indicates that a technology must not be so identified if a unilateral export control over it would:
>
> (i) harm domestic research into the identified "technology", such as through loss of investment, reduction in actual or projected cash flows, or the availability of qualified professionals necessary to develop it;
>
> (ii) be ineffective at preventing countries of concern from developing it indigenously or otherwise acquiring comparable technology from third countries;
>
> (iii) be imposed without a full consideration of the impact on the economy of the United States of such a control; or
>
> (iv) not likely be considered acceptable by the multilateral regime allies or be inconsistent with the standards for the types of controls that are subject to the multilateral regimes.

Each of the elements in the proposed definition is taken from the standards in ECRA and the notice. The proposed definition also uses as many of the existing EAR definitions and concepts as possible to avoid later confusion in its application. We thus request that it be formally adopted as the EAR's new definition of "emerging technology."

B. BIO Comment 2 – Justify Each Proposed Control

We also request that, for each technology identified in a proposed rule to be controlled as "emerging," BIS provide sufficient information regarding why the proposed control meets each of the foregoing draft definition's elements, which, again, mirror the relevant statutory standards. That is, for each proposed control on an emerging technology, BIS should describe in the notice (i) why it is "essential" to our national security; (ii) what the specific weapons-, military-, or intelligence-related application the control is designed to address; (iii) why the unilateral control would not harm domestic research, (iv) why it would be effective at stemming its proliferation to countries of concern; and (v) the results of its full consideration of the impact on the U.S. economy that would result from the unilateral control. Unless the public has sufficient information regarding what the specific and identifiable national security concern is to be addressed by control over a specific technology, it will not be able to provide useful comments consistent with the standards and goals of ECRA. Once such a national security justification is provided, the industry should be allowed an opportunity to respond before a designation is made.

IV. BIO'S RESPONSE TO BIS'S REQUEST REGARDING THE CRITERIA THAT SHOULD BE USED FOR DETERMINING WHETHER THERE ARE SPECIFIC TECHNOLOGIES THAT ARE IMPORTANT TO THE NATIONAL SECURITY OF THE UNITED STATES

A. BIO Comment 3 -- Emerging Technologies to be Identified Should be Specific Technologies that are not now Controlled and that are Essential to the National Security of the United States

Although the notice asks for advice about technologies that are "important" to the national security of the United States, ECRA section 4817 limits the scope of new emerging controls to those that are "essential" to the national security of the United States. We are not suggesting that "important" technologies not be controlled, but only that they be identified through the traditional process that involves submissions to the multilateral system. Because ECRA states that unilateral controls should be limited, a higher standard – the "essential" standard – is required in this effort.

In addition, any technologies identified and controlled under this rulemaking process should not include any previously identified and controlled technologies pursuant to existing regimes. The technologies to be identified and controlled pursuant to ECRA section 4817 may not include technology directly related to or required for the production, development, or use of military items because such technology is already controlled by the International Traffic in Arms Regulations (ITAR) and the EAR. The U.S. Munitions List (USML) and the "600 series" entries on the Commerce Control List (CCL) regularly updates and revises the lists of controlled technologies. When read together, the catch-all structure of these controls over identified technologies, even if without a positive or detailed description, already constitutes its control for export. For example, USML Category XIV(m) controls all technical data of any sort directly related to any of the toxicological and biological agents subject to the ITAR.

The technologies to be identified and controlled pursuant to this effort also do not include the technologies the United States and its allies have identified over several decades of non-proliferation efforts as being required for the development, production, or use of missiles, chemical, biological weapons, nuclear, and other weapons. In essence, the U.S. and its

allies have studied for decades the parts, components, and other items critical to developing, producing, or using such weapons of mass destruction (and their delivery systems) and have identified them in the regularly revised and updated multilateral export control lists, which the United States then implements in its export control lists, primarily the CCL. The structure of the technology controls for such items is such that they include all technology of any sort, whether emerging or mature, required for the development, production, or use of such items.

B. BIO Comment 4 – The Administration Needs to Identify the Specific National Security Threats to be Addressed by New Emerging Technology Controls that are Not Already Being Addressed

In light of the foregoing, BIO requests the U.S. Government explain the link between the existing catch-all controls over technology that address military and WMD threats and the current and emerging threats motivating this expedited technology control identification effort. The ANPRM does not identify the specific national security problems to be solved with new controls that are not already addressed by existing controls. While the ANPRM states general, traditional security concerns and, separately provides a list of "representative technology categories" in which "emerging technologies" could potentially exist, the notice does not connect the two issues. Neither BIO nor our members have the national security expertise or access to the intelligence of the U.S. Government to make this connection. Thus, it is for the Government to identify the threats to be addressed and for industry to provide its expertise regarding the technologies for how to address them.

We appreciate that the Government cannot release classified information to the public regarding threat assessments. Nonetheless, we respectfully request that the Administration clearly define in another notice or in its proposed rule the unclassified bases regarding what emerging technologies *essential* to the national security threats are not being addressed by existing controls. As with all other such threats identified over the decades, government and industry technologists can then work backwards to help identify the specific chokepoint and enabling technologies required to develop, produce, or use such items and to provide industry-standard definitions of key terms that will enable compliance with the controls.

We believe that identifying the specific national security concerns to be addressed by the new emerging technology controls will reduce uncertainty, and thus collateral economic harm to U.S. businesses. If foreign customers become uncertain about whether they will be able to continue to do business with or invest in U.S. companies, or that the new controls will be imposed for political or special interest economic reasons, then foreign customers will take their business to foreign competitors, which will injure the U.S. economy. Of particular concern is the "lock-out effect" that results from foreign customer uncertainty about whether U.S. companies can be reliable suppliers in light of the U.S. Government's trade policies. Even without an actual legal control, the perception of one or its possibility, can motivate foreign customers to design out and otherwise avoid U.S. content in order to have a certain, stable supply of the items they need.

C. BIO Comment 5 – Proposed Controls Should be Limited to Addressing National Security Concerns, not Trade Policy Issues

When providing a more detailed answer defining the national security threat that is not being addressed by current controls, we also respectfully request that the proposed controls explicitly clarify that the effort to use export controls is not intended as a tool of trade

policy, industrial policy, or trade protectionism, or otherwise as part of any government efforts to pick economic winners and losers among American companies. Such policy objectives are better addressed by other areas of law, which is one reason we believe ECRA's primary statement of policy in section 4811(1) is limited to achieving national security and foreign policy objectives and the scope of section 4817 is limited to controlling only those technologies "essential to the national security of the United States." Both provisions and BIS's notice conspicuously exclude industrial policy or trade protectionism as a policy purpose for export controls generally or new emerging technology controls specifically.

The Administration's November 17, 2017 National Security Strategy (NSS) states that "economic security is national security." In light of this policy position, we respectfully request that BIS and other export control officials who will be making decisions on which technologies to include and exclude from the scope of any proposed emerging technology controls take the NSS into account when doing so. In particular, Pillar II on page 17 states, in relevant part, that a "strong economy protects the American people, supports our way of life, and sustains American power. American workers thrive when they are free to innovate . . . [and] operate in markets free from excessive regulation and unfair foreign trade practices." Similarly, the first "priority action" on page 20 states that "Departments and agencies will eliminate unnecessary regulations that stifle growth, drive up costs for American businesses, impede research and development, discourage hiring, and incentivize domestic businesses to move overseas." Page 21 describes the need to "promote and protect the U.S. national security innovation base." Finally, page 23 describes the need to promote exports and to further America's technological edge.

Inherent in the creation and imposition of novel unilateral export controls is the risk that each of these NSS objectives will be violated if the control scopes are not narrowly tailored to specific, clearly identifiable national security threats with clear justifications. If the scope of the controls is too broad or vague, then the controls will be, by definition, unnecessary regulations that will stifle growth, drive up costs, impede research, and motivate domestic businesses to move overseas. The U.S. biotechnology industry is the leader of innovation in a highly globalized and competitive industry. The success of the U.S. biotechnology industry depends on access to global markets, leveraging a globalized and integrated supply chain, well-reasoned and consistent regulatory burdens to improve the safety and efficacy of biotechnological advances, and reliance on highly specialized talent from around the world. The ability to leverage these assets enables our industry's ability to maintain high-wage research, design, and manufacturing jobs in the U.S. The broad scope of biotechnologies being considered for possible controls are those with promising commercial potential, and it will be critical for the U.S. biotechnology industry to be able to compete globally in these emerging fields. The extent that the U.S. industry is locked out from engaging in these high growth markets—whether as a matter of law or perception—will place at risk the success of U.S. companies and the jobs and research investments that depend on their ability to compete for business in these fields. Small businesses, in particular, would be impacted the most. This, in turn, would diminish U.S. economic competitiveness and ultimately place U.S. national security, as defined in the NSS, at risk.

D. BIO Comment 6 –Emerging Technologies Identified for Control Should or Will Be Exclusive to the United States

We believe Congress required the Administration to consider the foreign availability of emerging technologies before imposing controls over them to avoid the imposition of

unilateral U.S. controls, which would be more harmful than helpful if the technologies were already available outside the United States. If a U.S. company is either not allowed to export a commercial technology or needs to shoulder significant regulatory burdens to do so, then it is, by definition, at a significant competitive disadvantage to its foreign competition that does not have such burdens. A goal of the NSS is to put U.S. companies on a level playing field with foreign competitors. Except when absolutely necessary for a clear national security reason, imposing unilateral controls could put U.S. companies at a competitive disadvantage from their foreign competitors and, for that reason, should be pursued with extreme caution.

Most of the technologies described in the ANPRM relevant to our members – particularly "Biotechnology, such as (i) nanobiology; (ii) synthetic biology; (iii) genomic and genetic editing; or (iv) neurotech" -- are the subject of intense global competition among companies, universities, and other research entities. To the extent that a particular technology is the subject of comparable research and product deployment by entities outside the U.S., such technologies should not be the subject of new unilateral controls. The controls would only harm the economic interests of the U.S. company without limiting the development or proliferation of the technology outside the United States.

When considering the issue of foreign availability, we request that BIS consider that, after technology moves beyond the fundamental research stage, companies will rarely have perfect or complete information about the technical capabilities of their competitors. They will have public information derived, for example, from websites and trade shows, but will not have proprietary information about their competitors' products. Thus, the best way to address this issue is to consider whether foreign companies or entities would or could easily step and fill the technology gap if the U.S. company were no longer allowed to export a particular technology. If foreign competitors can be identified, then the comparable technology should not be subject to the new controls. In addition, given the widely used practice in scientific innovation of publishing and disseminating research in academic and peer-reviewed journals, the existence of such publications, and ensuing patent filings, should be key indicators that biotechnologies in the "representative technology categories" are already being developed in foreign markets because the science underpinning such research is already publicly available.

F. BIO Comment 7 -- Emerging Technologies Should Not be Identified if a Unilateral Control would Harm Research into the Technology in United States

All export controls, by definition, impose burdens and costs on the development and export of controlled technologies. That is why they are export "controls," and warranted, as described in ECRA, only to the extent necessary to achieve specific national security or foreign policy objectives. Given the nature of the new controls to be considered pursuant to section 4817 and the already broad scope of existing controls that already address military and WMD applications, Congress, consistent with the NSS standards and those in ECRA section 4811(1), wanted to ensure that the new controls not harm domestic research into the very technologies it requires be protected.

The U.S. biotechnology industry is highly dependent on investment capital to fund the groundbreaking research and development that leads to innovative cures. On average, it costs over $2.6 billion to develop a single life-saving treatment and most companies spend a decade conducting research and development until their first therapy is approved by the

Food and Drug Administration (FDA). These factors underscore the importance of the ANPRM to the biotechnology sector, and the need to proceed with extreme caution before imposing unilateral export controls on biotechnologies that would undermine their ability to be developed in the U.S.

Thus, unilateral technology controls that would harm, whether as a legal, practical, or economic matter, the ability of U.S. biotechnology companies to conduct research in United States would be inconsistent with ECRA section 4817. Companies and other entities that conduct or benefit from such research directly or indirectly will generally have better access to information about how or whether a unilateral control would harm it than will the government. The technical and economic aspects of this information are also usually quite complex and company-specific. Thus, we respectfully request BIS to give great weight to the economic arguments to be made by companies regarding their technologies and whether the imposition of a unilateral control over a specific technology would or would not harm research in the technology in the United States.

G. BIO Comment 8 -- BIS Should Not Impose Controls over Emerging Technology that Would be Ineffective at Preventing their Proliferation to Countries of Concern

This fourth element of the section 4817 standards is a corollary to the previous three, which is that the Administration should not propose controls over emerging technologies that would not result in their being developed in or acquired from third countries. If a particular unilateral control would not prevent, for example, a comparable technology from being developed in a third country, such as China, or acquired from another foreign country, then it is, by definition, not a good candidate for a proposed control. Thus, we also request that BIS only propose unilateral controls if it has some reason to believe that, and can articulate why, the specific technology is unique to the United States and would remain so with the aid of an export control.

H. BIO Comment 9 -- BIS Should Neither Propose or Impose New Emerging Technology Controls unless it has Fully Considered the Impact Such Controls Would have on the U.S. Economy

ECRA section 4811(1) states that "it is the policy of the United States . . . to use export controls only after full consideration of the impact on the economy of the United States. . ." This requirement is similar to the objectives of the section 4817 standards but has a procedural element to it that we respectfully request BIS provide evidence of when it proposes any new controls over emerging technology. An unsupported statement regarding the economic impact of a new control would not be sufficient to meet the "full consideration" requirements of ECRA. Thus, as part of any proposed controls, BIS should also describe the basis for its full consideration of how or whether the proposed control would affect the U.S. economy.

The U.S. biotech sector is a key driver of U.S. economic growth and vitality. The biotech sector contributed $2 trillion to total economic output in 2016, provided an estimated 1.74 million employees with high-paying jobs (with an average annual salary of $99,000 in 2016, 85 percent greater than the average for the overall private sector), and reinvests more back into the local economy than any other sector.[4] Therefore, we believe it is incumbent on the U.S. Government to avoid harming domestic research and development into important and novel biotechnologies. The possibility of new export controls on the biotechnology sector

may drive away investors to other markets and regions. The biotech investment community, upon which smaller, pre-revenue companies rely, is deterred by uncertainty and undefined risk. Due to their long research and development periods and reliance on investment capital during that timeframe, such uncertainty may have a chilling effect on investments in pre-revenue companies operating within those broad technology fields.

We recognize the ANPRM's intent to identify "emerging technologies" and update the export control lists to ensure national security without hampering the ability of the U.S. commercial sector to keep pace with international advances. BIO supports the objective of balancing national security and innovation. However, placing restrictions on the export of technologies could disadvantage investments into the U.S. life sciences sector, thereby stifling advancements in life-saving therapies, innovative R&D, and manufacturing jobs. For instance, expansive export controls on emerging technologies in the life sciences sector could have a chilling effect on inward advancement from reputable multinational companies, who may choose to invest elsewhere. This would negatively impact future job creation in the U.S. and the development of high-value U.S. export sectors, which would run counter to the Administration's pro-growth economic agenda.

Similarly, we believe that there will be considerable concern in the investor and foreign business partner community that the United States will begin imposing broad controls over the large categories of emerging technologies identified in the ANPRM. Most do not appreciate that the ANPRM is a request for public input and information about how to narrowly tailor controls. Because perception can become reality with respect to economic decisions involving U.S. companies, we encourage the Administration to continue to roll out proposed new controls, only where absolutely essential, in as transparent a manner as possible in order to reduce uncertainty.

Further, if the flow of technology and information is disrupted by a requirement for export licenses for technology, product delivery will be delayed. Ultimately, this will cause higher cost and delays in bringing solutions to U.S. farmers, patients, and companies. The inability to quickly and cost effectively apply technology to the global marketplace will directly and adversely impact U.S.-based biotechnology companies.

I. BIO Comment 10 -- BIS Should Propose and Impose Controls that are Tailored to Focus on Core Technologies

The requirement in ECRA for "tailored" controls on "core technologies" demonstrates that Congress recognized the need for precise, clear, and industry-standard definitions of the new terms to be used in the proposed new controls. By definition, the new controls will pertain to technologies that are not yet mature. The industries in each of the sectors identified in the ANRPM are still evolving. There will be many competing or different understandings of the words used. Thus, the usual EAR approach of relying upon industry-standard definitions of technologies will thus not be as successful with this effort.

Another key element to ensuring that proposed controls are tailored is that they track the existing ECCN structure and EAR definitions, such as "technology," "development," and "required." These elements have been worked out and refined over decades of interaction with industry and our regime counterparts. Although complex, they are nonetheless a well-tested, coherent general structure of controls and definitions. They allow the government to accomplish its national security objectives in a way that can be understood and complied with by domestic and foreign industry. Moreover, the structure and definitions largely

prevent inadvertent over-controls of technology, or portions of technology, that can merely be capable for use with a sensitive item but do not warrant control because they are common to non-sensitive applications. Following the existing EAR structures and definitions will not limit the ability of BIS to identify and to control critical know-how because the EAR's definition of "development" applies to technology at all stages prior it being in serial production.

J. BIO Comment 11 -- Proposed Controls on Emerging Technologies Should be of a Type That will Likely be Considered Acceptable by the Relevant Multilateral Regime and Consistent with the Types of Technologies Controlled by the Regimes.

ECRA section 4817(c) requires the Administration to propose to the relevant multilateral export control regime that any new technologies identified for control as "emerging" be added to the regime's control list. If after three years of effort the Administration fails to do so, then Commerce must consider "whether national security concerns warrant the continuation of unilateral export controls with respect to that technology." We are not suggesting that ECRA prohibits unilateral controls. Rather, to stay consistent with ECRA's statement that unilateral controls are discouraged and for this regime submission mandate to have a good faith chance of being complied with, BIS, working with its interagency colleagues, will need to propose controls that have a reasonable chance of being accepted by the regime members and that are consistent with the standards for what the relevant regime controls. It is not necessary to repeat for the government the scope of the Missile Technology Control Regime, the Australia Group, the Nuclear Suppliers Group, or, most importantly, the Wassenaar Arrangement. Rather, we suggest that, in light of section 4817(c), BIS identify how and why any proposed controls on emerging technologies be within the scope of the relevant regime.

Given the potential harm unilateral controls could impose on the U.S. biotechnology industry as described above, we ask BIS to go one step further and delay implementation of any controls over newly identified emerging technologies until after the relevant multilateral regime has also agreed to identify the same technology on its control list. We believe that such an action would be within the scope and spirit of ECRA, which emphasizes the well-tested policy conclusions that (i) multilateral controls are far more effective than unilateral controls and (ii) unilateral controls should be used only in exceptional cases because they generally harm U.S. companies more than their competitors without necessarily depriving a country of concern the technology at issue.

V. CONCLUSION

We respectfully request that the Administration not propose or otherwise implement unilateral controls pursuant to ECRA section 4817 if a new control on a specific category or type of technology:

1. would not be *essential* to the national security interests of the United States based on the notice's description of what constitutes an essential national security interest;

2. is available or is being developed outside the United States;

3. would harm research into the technology in the United States;

4. would fail to prevent the technology from being developed in, or otherwise acquired by, a country of concern;

5. was not proposed after a full consideration of the impact such controls would have on the U.S. economy;

6. is not *tailored* to focus on core technologies;

7. is not limited to protecting *specific* United States national security interests; or

8. is of a type that is not likely to be considered acceptable to the multilateral regime allies or is inconsistent with the standards for the types of controls that are subject to the multilateral regimes.

* * *

Thank you again for conducting this process to identify emerging technologies that are essential to national security that are not now controlled but should be pursuant to the standards in ECRA. If you have any additional questions or would like to discuss these comments further, please contact Lisa Schaefer, Director of Financial Services Policy at Lschaefer@bio.org.

Sincerely,

Tom DiLenge
President
Advocacy, Law & Public Policy Division

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[1] Journal of Health Economics, Joseph A. DiMasi, Henry G. Grabowski, Ronald W. Hansen, "Innovation in the pharmaceutical industry: New estimates of R&D costs," 12 February 2016, https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291.

[2] A recent ITIF study indicated that "59 percent of biopharmaceutical executives said finding and retaining the best talent is somewhat to very challenging, and higher than any other competitive factor," which underscores the importance of preserving access to skilled labor for the U.S. biotechnology industry. See Joe Kennedy, Information Technology & Innovation Foundation, "How to Ensure That America's Life-Sciences Sector Remains Globally Competitive," March 2018, http://www2.itif.org/2018-

life-sciences-globally-competitive.pdf?_ga=2.55726563.973572407.1543611078-15769970.1543611078, page 36.

[3] Ibid.

[4] TEConomy/BIO report, "Investment, Innovation and Job Creation in a Growing U.S. Bioscience Industry," 2018, https://www.bio.org/sites/default/files/TEConomy_BIO_2018_Report.pdf.